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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ron S. Israeli et al.

Serial No.: 08/470,735 Group Art Unit: 1645

Filed : June 6, 1995 Examiner: S. Gucker

For : PROSTATE-SPECIFIC MEMBRANE ANTIGEN AND USES THEREOF

1185 Avenue of the Americas
New York, New York 10036

Assistant Commissioner for Patents
Washington, D.C. 20231

SIR:

SECOND DECLARATION OF PAUL KALADAS, Ph.D. UNDER 37 C.F.R. §1.132

I, Paul Kaladas, Ph.D., hereby declare that:

1. I am a coauthor of the abstract attached hereto as Exhibit 1, Feng et al. entitled "Purification and Biochemical Characterization of 7E11-C5 Prostate Carcinoma Associated Antigen," Proceedings of the American Association For Cancer Research, volume 32, March 1991.
2. At the time the Feng et al. abstract was prepared, I was Group Leader, Immunochemistry, at Cytogen Corporation, and was responsible for the development of analytical methods used in support of product development. As such, I was directly involved in the research leading to the abstract and in the preparation of the abstract.
3. Prior to publication of the Feng et al. abstract, neither the 7E11-C5 prostate carcinoma associated antigen nor a

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nucleic acid encoding it had been isolated or characterized.

4. The description of the 7E11-C5 prostate carcinoma antigen in the Feng et al. abstract would not enable one skilled in the art to make the 7E11-C5 antibody per se. Moreover, in order to make an antibody having the properties of the 7E11-C5 antibody referred to in the Feng et al abstract, one skilled in the art would have needed to obtain the purified 7E11-C5 prostate carcinoma associated antigen referred to in the Feng et al abstract. However, to obtain the purified 7E11-C5 prostate carcinoma associated antigen, one skilled in the art would have needed to have either (i) an antibody such as the 7E11-C5 antibody referred to in the abstract, (ii) a hybridoma cell line such as the one which produces the 7E11-C5 antibody, or (iii) a nucleic acid encoding the antigen. None of these were publicly available as of either the publication date of Feng et al. or as of November 5, 1992, the priority date of the above-identified application.
5. Although I and my coauthors had access to the 7E11-C5 antibody, our access was restricted and we were not entitled to make the 7E11-C5 antibody available to others. Moreover, to the best of my knowledge and belief, neither (i) the hybridoma cell line which produced the 7E11-C5 antibody, (ii) the 7E11-C5 antibody per se, (iii) a similar antibody which recognized the 7E11-C5 prostate carcinoma antigen, nor (iv) a nucleic acid encoding this antigen were publicly available as of either the date on which the Feng et al abstract was distributed to the public or as of November 5, 1992, the priority date of the above-identified application. Moreover, the abstract

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does not describe properties of the 7E11-C5 prostate carcinoma antigen or any procedure that would have enabled one skilled in the art to obtain the antigen in purified form without the use of a specific antibody such as the 7E11-C5 antibody. Therefore, the abstract necessarily did not enable one skilled in the art either (i) to obtain purified 7E11-C5 prostate carcinoma associated antigen, or (ii) make the 7E11-C5 antibody per se or a similar antibody.

I hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that any such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 2/28/00

Paul M. Kaladas
Paul Kaladas, Ph.D.